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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT PAPER NUMBER

1654

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/702,550	Applicant(s) CHERDSHEWASART, WICHAI	
	Examiner Christopher R. Tate	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/830,455.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1103</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1 and 2 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the term "*Butes*" (recited twice). It is unclear as to what this term is actually defining, especially since no plant known as *Butes superba* could be found in an extensive patent and non-patent literature search of the claimed subject matter - is this a typo? It would appear that this term is attempting to define the plant genus --*Butea*--. Claim 1 should be amended accordingly.

Claim 2 depends from claim 1 and is, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Pangsrivongse (Rev. Filipina Med. Farm., 1938 - CAPLUS abstract), by Schoeller et al. (US 2,112,712), by Schoeller et al. (US 2,136,397), or by Vatna (Thai Schi. Bull., 1939).

A water or lower alcoholic extract obtained from the tubers, roots, stems, leaves and/or tissue-cultured calluses of *Butea superba* is apparently claimed.

Each of the cited references teach water (aqueous) or lower alcoholic extracts obtained from the roots and/or other parts of the plant *Butea superba* (see, e.g., Pangsrivongse - abstract; '712 - page 1; '397 - pages 1-2; Vatna - abstract).

Therefore, each of the cited references is deemed to anticipate the instant claim above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being obvious over Pangsrivongse (Rev. Filipina Med. Farm., 1938 - CAPLUS abstract), the admitted state of the art, and the reference entitled "Thailand: Thai Equivalent Viagra Drug Unveiled" (source: Nation - PROMT Newsletter Abstract, March 24, 1999).

A water or lower alcoholic extract obtained from the tubers, roots, stems, leaves and/or tissue-cultured calluses of *Butea superba*; as well as a method of treating erectile dysfunction or malfunction by administering such an extract to a male in need thereof is claimed.

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Pangsrivongse beneficially teaches that the root of *Butea superba* is esteemed as a "rejuvenating drug" in Siam and, further, that active principles were effectively obtained therefrom via alcoholic extraction (see CAPLUS abstract). In addition, as readily admitted by Applicant, the tubers (roots) of *Butea superba* have long been used in the prior art as a raw material for invigorating males in Thailand (see, e.g., page 2, lines 1-3, of the instant spec.).

The PROMT Newsletter Abstract beneficially teaches a potency pill (or pharmaceutical gel or capsule) containing red kwao krua (which, as readily admitted by Applicant is also known as *Butea superba* (see, e.g., page 1, line 13 of the instant specification) which is disclosed as enabling the user to increase sexual potency and as being the Thai equivalent to the drug Viagra (a drug which is extremely well known in the art to be used to effectively treat erectile dysfunction/ malfunction when administered to a male in need thereof).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat erectile dysfunction/malfunction via administering a pharmaceutically effective amount of an alcoholic extract of *Butea superba* roots/tubers to a male in need thereof, based upon the beneficial teachings provided by the cited references, as well as that which is admittedly well known in the prior art, with respect to the art-recognized Viagra-like rejuvenating invigorating properties of this plant. The adjustment of particular conventional working conditions (e.g., using a conventional lower alcohol solvent such as methanol or ethanol - both of which are commonly employed and notoriously well recognized within the herbal art as being effective alcoholic extraction solvents) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'C. Tate', with a stylized flourish.

Christopher R. Tate
Primary Examiner
Art Unit 1654